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VIA ECF FILING ONLY

Hon. Lorna G. Schofield, U.S.D.J.
United States District Court, SDNY
500 Pearl Street
New York, NY 10007

Re: Powers v. Memorial Sloan Kettering Cancer Center, et al.
Docket No. : 1:20-cv-02625

Dear Judge Schofield:

Defendants respectfully submit this letter motion seeking the Court to deem the uncontested Local Rule 56.1 statements of fact admitted for purposes of trial. In preparing the Proposed Joint Final Pretrial Order, Plaintiff's counsel refused to stipulate to the numerous facts Plaintiff had not contested in Defendants' Local Rule 56.1 Statement of Material Facts. Plaintiff's counsel directed Defendants to file this letter motion.

On August 16, 2021, Defendants filed a motion for summary judgment, along with their Local Rule 56.1 Statement of Material Facts that is properly supported by evidence in the record. (Doc. 231). Plaintiff filed his Response to Defendants' Local Rule 56.1 Statement of Material Facts on September 16, 2021. (Doc. 235-1). Plaintiff's Response did not contest the below facts, which facts should be deemed admitted for trial.

Plaintiff's position that these facts are "not uncontested for the purposes of trial" has no merit given plaintiff's prior representations to the Court that these facts were not contested. See Local Civil Rule 56.1; see also Gallimore-Wright v. Long Island R. Co., 354 F.Supp.2d 487, 483 (S.D.N.Y. 2005) (accepting as true the assertions not responded to in defendant's Rule 56.1 statement and deeming those facts admitted at trial).

2. The decedent, Erika Zak, and Plaintiff were married in 2009.

3. In early [redacted] 2014, Ms. Zak gave birth to her daughter.

4. On April 8, 2014, Ms. Zak underwent a CT scan that revealed numerous heterogeneous masses involving all segments of the liver, and a large pelvic mass.

5. On April 10, 2014, Ms. Zak underwent a liver biopsy that was aborted due to a liver laceration with sudden dizziness, tachycardia and hypotension requiring urgent transfer to the ICU for management of hemorrhagic shock.

6. The liver biopsy confirmed metastatic adenocarcinoma.

7. On April 21, 2014, Ms. Zak underwent a colonoscopy, which confirmed an adenocarcinoma cecal mass; the KRAS mutation was detected.

8. On April 23, 2014, Ms. Zak presented to oncologist, Dr. Andrew Ko, at University of California San Francisco ("UCSF") and was told she had very advanced, metastatic colon cancer involving her liver and pelvis requiring systemic therapy.

10. Between May and August 2014, Ms. Zak received eight cycles of systemic chemotherapy (FOLFOX) with five of those cycles including Bevacizumab.

11. Dr. Nancy Kemeny, an employee and medical oncologist at Memorial, specializes in the treatment of colorectal cancer with liver metastasis.

12. In July 2014, Ms. Zak presented to Dr. Kemeny for consideration of a hepatic artery infusion ("HAI") pump, which Dr. Kemeny explained administered higher concentrations of chemotherapy directly to the liver.

17. On September 24, 2014, Ms. Zak was informed that a side effect of FUDR HAI pump treatment was liver toxicity.

18. On September 24, 2014, Ms. Zak started liver-directed FUDR via the HAI pump (156 mg) concurrently with systemic FOLFIRI every two weeks.

19. During the course of treatment, Dr. Kemeny monitored Ms. Zak's liver function tests ("LFTs") for elevations that would necessitate modifying or stopping FUDR HAI pump treatment.

20. As of the second cycle of FUDR HAI treatment, on October 22, 2014, Dr. Kemeny reduced FUDR to a slightly lower dose (to 117 mg).

21. The third cycle of FUDR was held on November 19, 2014 because Ms. Zak's liver enzymes were elevated.

22. On February 4, 2015, Ms. Zak resumed FUDR HAI treatment at a further reduced dose of FUDR (30 mg).

26. On April 1, 2015, Dr. Kemeny increased the dose of FUDR (100 mg) and added Mitomycin (16 mg) in an effort to reach a point where resection was possible.

27. Ms. Zak was unable to tolerate the dose of Mitomycin, and on April 29, 2015, Dr. Kemeny dose reduced Mitomycin (8 mg) and reduced her systemic chemotherapy.

28. On July 8, 2015, Dr. Ko eliminated Irinotecan from every other cycle of FOLFIRI because of cumulative treatment-related asthenia (fatigue), risk of chemotherapy-associated steatohepatitis, and a plateau in response.

29. On July 22, 2015, Dr. Kemeny dose reduced FUDR (to 50 mg).

30. In November 2015, Ms. Zak moved back home to Oregon where her parents were, and Ms. Zak transferred her local care to Oregon Health & Science University ("OHSU").

31. On November 10, 2015, Ms. Zak met with OHSU Social Worker, Caroline Macuiba, LCSW; Ms. Zak reported that since her husband did not work, he helped care for her and her almost two year old daughter.

33. On March 21, 2016, a PET/CT scan performed at Memorial demonstrated a new uptake in segment 7 of the liver consistent with new or re-emergent metastasis.

34. On March 21, 2016, Dr. Kemeny discussed these findings with Ms. Zak, as well as Dr. DeMatteo, and surgery was scheduled for March 24, 2016.

36. Ms. Zak agreed to proceed with and consented to surgery.

37. On March 24, 2016, Dr. DeMatteo performed a "very difficult" operation during which he resected the PET positive tumor that was right behind the right hepatic vein; Dr. DeMatteo also performed surgical microwave ablations of two lesions.

41. On June 22, 2016, Ms. Zak presented to Dr. Kemeny; Ms. Zak was accompanied by her brother-in-law, Stephen Powers ("Stephen"), who tape recorded the visit.

44. Dr. Kemeny further dose reduced FUDR (to 25 mg) and Mitomycin because Ms. Zakk's liver enzymes were slightly elevated.

45. On August 16, 2016, a PET/CT scan identified a new hypodense FDG avid hepatic segment 2 lesion consistent with viable metastasis.

47. Dr. Kemeny discussed the findings of the August 16, 2016 PET/CT scan on August 17, 2016 and Dr. Kemeny recommended percutaneous ablation of the new metastatic lesion.

48. Dr. Sofocleous was at all relevant times, and still is, a board-certified interventional radiologist who specializes in interventional oncology and is an employee of Memorial.

52. On August 29, 2016, Dr. Sofocleous performed a successful PET/CT guided ablation of the liver metastasis.

54. On October 5, 2016, Ms. Zak received a dose of FUDR (25 mg).

57. On November 30, 2016, Ms. Zak's dose of FUDR was held.

62. On March 21, 2017, a PET/CT scan demonstrated new FDG avid segment 7 and segment 4 lesions suspicious for recurrent metastases.

63. On March 22, 2017, Ms. Zak presented to Memorial with her sister-in-law Chloe Metz ("Ms. Metz"), who audio taped the visits with Dr. Kemeny and Dr. Sofocleous.

64. Dr. Kemeny explained to Ms. Zak that her scans showed two new lesions in her liver and she was going to ask Dr. Sofocleous about ablating the lesions.

66. Dr. Kemeny asked Ms. Zak to sit in the waiting room while she spoke with Dr. Sofocleous.

72. Since Dr. Kemeny had discussed with Dr. Sofocleous whether he thought an ablation was possible, Dr. Kemeny did not send Ms. Zak's case to a MDTB before referring Ms. Zak to Dr. Sofocleous on March 22, 2017.

81. Dr. DeMatteo did not see Ms. Zak in March or April 2017 prior to the ablation.

93. On March 22, 2017, Dr. Kemeny referred Ms. Zak to Dr. Sofocleous to evaluate whether liver-directed therapy by ablation was feasible.

100. In a study of perivascular tumors, the median distance between the vessel and edge of the tumor for microwave ablation was 2.5 mm.

101. It was anticipated that the blood flowing in the left portal vein that was in close proximity to Ms. Zak's lesion would dissipate the ablation heat.

103. Dr. Sofocleous believed he could completely treat Ms. Zak's perivascular tumor without damaging the portal vein.

104. According to Plaintiff's expert, Dr. Navuluri, Dr. Sofocleous' access to a PET-CT scan during the percutaneous ablation allowed for remarkably precise targeting of the lesions and placed Dr. Sofocleous at an advantage.

110. Dr. Sofocleous explained to Ms. Zak that he was going to ablate the lesions with the use of a PET scan and the areas that lit up, he would burn provided it was safe.

117. Dr. Sofocleous considered any other risks of ablation to be remote.

119. When discussing risks of a procedure, the standard of care is to describe the most common potential risks; it is not feasible for a provider to describe every potential risk.

122. On March 22, 2017, Ms. Zak asked a number of questions, which Dr. Sofocleous answered.

123. On March 22, 2017, Ms. Zak hoped Dr. Sofocleous could say no to her doing chemotherapy that week.

125. Dr. Sofocleous documented "A total of 55 minutes was spent face-to-face with the patient," which was a computer-generated template in the EMR that automatically populated when Dr. Sofocleous entered 55 minutes.

126. Dr. Sofocleous spent half of the 55 minutes face-to-face with Ms. Zak; the other half was spent reviewing Ms. Zak's case and the images, and deciding on the plan.

128. Plaintiff's expert, Dr. Navuluri, testified that the total discussion time for informed consent is not determinative of the adequacy of the consent.

130. Ms. Zak was an intelligent patient who did her research.

132. Ms. Zak underwent the ablation so that she could improve her chances of staying alive.

134. If Dr. Sofocleous had informed Ms. Zak of the risk of portal vein thrombosis, he would have told her he did not think the portal vein would be injured.

135. On April 10, 2017, Dr. Sofocleous performed PET/CT-guided percutaneous microwave ablations of the two liver lesions using a NeuWave ablation machine.

136. The standard of care was to achieve a minimum 1 cm margin around each tumor in order to effectively and fully eradicate each tumor.

137. Dr. Sofocleous used two probes to ablate each lesion as a "bracket" technique in order to limit the chance of spreading the tumor.

141. Running a second ablation is a technique used in interventional oncology practice to ensure no cancer cells are left behind.

142. Dr. Sofocleous documented a summary of the total time ablated for each lesion as 20 minutes with the energy ranging from 40-60 Watts.

143. When Dr. Sofocleous performed an additional ablation on the same spot without moving the needle, Dr. Sofocleous did not include that in his documented total ablation time.

145. According to a study on percutaneous microwave ablations, the total ablation time per tumor ranged from 3.5 to 40 minutes with a median time of 18 minutes.

149. Plaintiff's expert, Dr. Navuluri, testified that vessels adjacent to a tumor interfere with the ability to eradicate cancer, which is the phenomenon called the heat sink effect, and that additional energy is needed to eradicate cancer in a perivascular tumor.

150. At the end of the ablation, Dr. Sofocleous performed a PET scan and he noted "significant edema compromising the main and left portal vein with diminished flow in particular to the left liver segments 4 and 2."

152. A complication during a procedure does not mean the procedure was performed below the standard of care.

153. When there is no perfusion to cool the tissue, the tissue and additional tissue will burn and ablate.

155. Plaintiff met and spoke with Dr. Sofocleous immediately following the ablation; Dr. Sofocleous told plaintiff that he got the tumors, but there was some damage and reduced blood flow that needed to be monitored.

158. Immediately after the ablation on April 10, 2017, Ms. Zak's ALT was 341 and her AST was 472.

161. An ultrasound performed on April 11, 2017 demonstrated that the main and right portal veins were patent with correct direction in flow; in the left portal vein, there was no flow, but a collateral (side branch) vessel demonstrated portal venous flow.

163. The April 13, 2017 CT scan was suspicious for active extravasation (bleeding) in the liver.

164. On April 13, 2017, Dr. Amy Deipolyi performed a hepatic arteriogram; the two areas of concern for bleeding were selectively catheterized and found not to have active bleeding; no embolization was necessary or performed.

165. The April 13, 2017 arteriogram demonstrated multifocal arterial stenosis that was likely from prior locoregional therapy.

167. On April 14, 2017, a drain was placed for a suspected bile leak.

169. Ms. Zak returned home to Oregon soon after her discharge from Memorial on May 2, 2017.

170. On May 10, 2017, Ms. Zak's bilirubin was 1.2.

171. On May 16, 2017, Ms. Zak's case was presented to OHSU's Multidisciplinary Liver Tumor Board; it was noted that the ablation resulted in a large biloma with two drains placed; the recommendation was to follow Ms. Zak conservatively with scanning for evidence of biloma progression.

172. On June 26, 2017, a CT scan of the abdomen showed a decreased central biloma collection; the left portal vein thrombosis was stable with multiple collaterals noted throughout the abdomen and pelvis, as well as the retroperitoneum.

173. On June 27, 2017, Ms. Zak's case was presented to OHSU's Liver Conference; her central biloma had slightly decreased; she had two small growing lesions worrisome for residual/recurrent disease and single-agent chemotherapy was to be considered.

174. On July 4, 2017, Ms. Zak underwent an embolization of hepatic artery bleeding; the site of extravasation was from the proper hepatic artery just distal to the HAI pump in the gastroduodenal artery.

176. It is common for pump patients to require embolization of the hepatic artery because the catheter sits in the artery, and the artery used for the pump weakens over time.

177. On July 4, 2017, there was visualization of intrahepatic portal collaterals with no evidence of portal bleeding.

178. Dr. Navuluri testified that after the portal vein had occluded during the ablation, Ms. Zak's body was working to reperfuse the area and collaterals developed to reperfuse that portion of the liver.

179. On August 7, 2017, a PET scan was concerning for metastatic disease in segment 5 of the liver.

180. In October 2017, Ms. Zak was started on Pembro.

183. In December 2017, Dr. Kemeny told plaintiff that Cleveland Clinic was beginning to do transplants on patients, such as patients with biliary sclerosis from pump treatment.

184. In December 2017, Ms. Zak was evaluated at Cleveland Clinic for evaluation for an experimental liver transplantation protocol for patients with metastatic colon cancer to only the liver.

185. On February 1, 2018, Ms. Zak was approved by Cleveland Clinic to be on the liver transplant list.

186. United Healthcare initially denied Ms. Zak's coverage for a liver transplant; Ms. Zak went through an appeals process, and in May 2018, United Healthcare approved Ms. Zak's liver transplant.

190. Patients treated with HAI pumps always have some damage to their biliary system because the HAI pump delivers the FUDR chemotherapy to the hepatic artery, which supplies the entire biliary tree and bile ducts, and the FUDR is toxic to the bile ducts; the course is unpredictable and some patients require bile drains and other interventions.

191. FUDR toxicity typically affects the central bile ducts in the area of the porta hepatis, but as the disease worsens over time it goes throughout the rest of the liver.

194. In June 2018, Ms. Zak moved to Cleveland, Ohio.

197. On August 22, 2019, a donor liver became available for Ms. Zak and she was taken into transplant surgery.

210. There is no evidence that Dr. Sofocleous acted outside of his scope of employment at Memorial when he performed the ablation.

212. For nearly 3.5 years prior to April 10, 2017, Ms. Zak had not worked because she was on medical disability for Stage IV cancer.

Respectfully submitted,

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/s/ Betsy D. Baydala

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cc: via ECF filing

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